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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/015,540	12/11/2001	Nicholas Ling	690068.405C3	4186

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EXAMINER

BORIN, MICHAEL L

ART UNIT PAPER NUMBER

1631

DATE MAILED: 10/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/015,540

Applicant(s)

LING ET AL.

Examiner

Michael Borin

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09/20/2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 30-34, 73 and 74 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 30-34, 73 and 74 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

1. Claims 30-34,73,74 are pending. Claim 30 is amended.
2. Applicant's arguments filed 09/27/2004 have been fully considered and they deemed to be persuasive. Rejection under 35 U.S.C. 112, second paragraph, is withdrawn in view of amendment to the claims. Double-patenting rejection over US U.S. Patent No. 6,329,499 is withdrawn in view of filing Terminal Disclaimer. Rejection under 35 U.S.C. § 103 as obvious over Wucherpfenig et al. in view of Nishimoto et al. is withdrawn in view of Declarations of Gaur et al swearing behind the reference of Wucherpfenig et al.
3. Upon further review of this and other co-pending applications of the applicant the following new grounds of rejection were deemed to be necessary. Accordingly, the finality of the previous Office action is withdrawn. The following rejections constitute the complete set presently being applied to the instant application

Double Patenting

4. Claims 30-34, 73, 74 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over U.S. Patents No. 6369033 (claims 1-10), 6489299 (claims 1-4), and 6740638 (claims 1-4) in view of Nishimoto et al.

The claims of all three patents are drawn to peptide analogues comprising residues 87-99 of human myelin basic protein wherein Lys residue at position 91 is altered to another amino acid. U.S. Patent No. 6,329,499. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of U.S. Patent No. 6,329,499. are drawn to peptides with substituted Lys-91, and, optionally N- or C-terminal residues (claim 7) or other residues (claims 1,2). The referenced analogs are intended to be used for pharmaceutical purposes, such as treatment of multiple sclerosis. The claims of the referenced patents do not recite substitution of N- and/or C-terminal residues with D-amino acid residues.

Nishimoto teaches that replacement of an L-amino acid residue with the corresponding D- isomer is a standard way of rendering the polypeptide less sensitive to proteolysis. See col. 15, line 2.

As the referenced analogs are intended to be used for pharmaceutical purposes, such as treatment of multiple sclerosis, it would have been obvious to

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an artisan at the time the invention was made to be motivated to alter the terminal amino acid residues of MBP peptide analogs from L- to D-isomers to reduce proteolysis and thus to increase stability of the analogs.

Claim Rejections - 35 USC § 103.

5. Claims 30-34, 73, 74 are rejected under 35 U.S.C. § 103 as obvious over Martin et al (J. Immunology, Vol. 148, pages 1359-1366) in view of Nishimoto et al.

Martin et al teaches peptides comprising residues 88-100 of human myelin basic protein with the lysine at residue 91 altered to be Ala. The peptides are synthesized by solid phase synthesis. See, e.g., page 1360, column 1, fourth full paragraph, and Figure 3, peptide A1a5 (or Ala5). Note that because of a different numbering system, the Martin et al article's residues 88-100 correspond to the same fragment of MBP as applicants' residues 87-99. Sufficient evidence of similarity is deemed to be present between the peptide of the Martin et al article and Applicants' claimed peptide analogues to show the burden to Applicants to provide evidence that the claimed peptide analogues are unobviously different than those of the Martin et al article. Because the peptides of the Martin et al article

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were used in *in vitro* cell cultures, inherently they must have been combined with a physiologically acceptable carrier or diluent.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (571) 272-0713. The examiner can normally be reached on 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-0722. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Michael Borin, Ph.D.
Primary Examiner
Art Unit 1631

10/12/04